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The purpose of this randomized clinical trial is to evaluate the impact of an advanced practice nurse on the cost of care and quality of life for women newly diagnosed with breast cancer. The control group receives standard medical care while the experimental group receives standard medical care plus advanced practice nursing care. Of the patients eligible for the study, 71% (211 women) agreed to participate, with an attrition rate of 11%. Interventions of the advanced practice nurses (APN) including coordination of care, education, and support are ongoing with patients in the experimental group. Preliminary analysis of the Mishel Uncertainty in Illness Scale (MUIS) at one month showed that patients receiving APN interventions had significantly better scores on the sub-scales of complexity (understanding the system of care), inconsistency (receiving consistent information), and unpredictability (contingency between illness, treatment cues and illness outcomes), than the control group ($p < 0.01$). Intervention subjects also had less depression at one month ($p<0.05$). No statistical differences were found in other scores during this acute intervention phase. In 1999, final analysis will be conducted on cost outcomes using charge and reimbursement data and quality of life outcomes using the FACT-B, POMS, and the MUIS.

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Laurie J. Ritz 10/22/97

PI - Signature Date

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INTRODUCTION

Breast cancer accounts for almost one third of all cancers in women in the United States (US). Greater than 180,000 new cases will be diagnosed in 1997 alone. Almost 44,000 women will die of breast cancer this year.[1] Cost-effective methods to manage care for individuals with breast cancer while continuing to achieve quality outcomes is a major US public health goal.

As costs decrease, it is unclear if quality outcomes are being maintained. In addition, factors including access to care, intricacy of the health care system, numerous caregivers, complexities of the diagnostic tests and procedures, and technical components of treatment can overwhelm patients and result in compromised quality outcomes.

An Advanced Practice Nurse (APN) could serve as a facilitator to ease the breast cancer patient's way through the health care system providing quality care in a cost-effective manner. The former Office of Technology Assessment of the US Congress conducted a comprehensive review of 286 studies on the cost and effectiveness of APNs. Their findings from this review indicated that within the APN's area of competence, they communicate better with patients, concentrate more on prevention, and provide more education than physicians. Patients are satisfied with care, access to care is less complicated, and the costs of care are less with the interventions of the APN.[2]

Studies focused on lung cancer patients, low birthweight infants, myocardial infarction patients, cardiovascular surgical patients, HIV-infected individuals, children with chronic diseases, and hospitalized elderly have demonstrated the effectiveness of advanced nursing care with improved outcomes and reduced health care costs, but none have focused on women with breast cancer.[3-11]

This study was designed to focus on women with breast cancer by testing the following hypotheses:

- Women with newly diagnosed breast cancer who receive continuity of care through advanced nursing care/interventions across the various health care settings will achieve a better quality of life than patients who do not receive advanced nursing care.

- Women with newly diagnosed breast cancer who receive advanced nursing follow-up care/interventions will have a lower cost of care than patients who do not receive advanced nursing care.

METHODS

Setting

The setting for this study is HealthSystem Minnesota, an integrated health care system in a suburban community of Minneapolis, Minnesota. This system includes Methodist Hospital, Park Nicollet Clinic, Primary Physician Networks, The Foundation, and the Institute for Research and Education. There are approximately 6000 employees, including more than 450 physicians. HealthSystem Minnesota has played a leadership role in cancer care in Minnesota since 1976 when it was first accredited by the American College of Surgeons Commission on Cancer (ACSCC). The Cancer Program is currently designated as a Teaching Hospital Cancer Program by the ACSCC, offering a complete range of diagnostic, treatment, education, research, and support programs. Methodist Hospital is a non-profit, acute care, community hospital with 426 beds. In addition to this system, Fairview Ridges (a 150-bed hospital located 25 miles from Methodist Hospital) was added as a site in October 1996. The same HealthSystem Minnesota physicians deliver care at Fairview Ridges for the system's patients in this suburban community and surrounding areas.

Sample

Enrollment to this study is completed. The study sample is female breast cancer patients ≥18 yrs old who were newly diagnosed and/or were treated at HealthSystem Minnesota between February 1995 and May 1997. They were identified through pathology departments of both participating hospitals for potential participation in this randomized clinical trial. Physician referral was requested and eligibility criteria was checked. Participant eligibility required newly diagnosed women to give informed consent, read and write English, and complete questionnaires. Ineligible women had a previous diagnosis of cancer, severe psychiatric illness, or comorbidity limiting functional ability. In addition, enrollment into the study required women to plan their care within the health system and to give their consent within two weeks of diagnoses. Women who participated from the added site of care met the same eligibility criteria as those of the original site. After the eligibility criteria were met and informed consent was obtained, the women were randomly assigned into one of two groups: women in the control group received standard medical care while women in the intervention group received standard medical care plus advanced nursing care.

Intervention

The two-year intervention is completed for twenty women who were randomized to the intervention arm of the study. The intervention is advanced nursing care which consists of follow-up care and interventions based on Brooten's work[12] and the standards of advanced practice in oncology nursing.[13] It includes coordination of care, assessment and

monitoring of symptoms, direct care, patient and family education, consultation with other health care services, utilization of current research findings, and establishment of standards of practice. Care is individualized to patient and family needs, based on the expressed needs of the individual, the assessment of the APN, and other health care providers' evaluations. A detailed description of the APN's standard follow-up care as previously reported in 1996 is in Appendix A.

Data Collection

Quality of Life

Quality of life is measured using three questionnaires including, the Functional Assessment of Cancer Therapy (FACT-B), Profile of Mood States (POMS), and Mishel Uncertainty in Illness Scale (MUIS). The FACT-B is a 44-item tool measuring self-reported quality of life in individuals with breast cancer. Six sub-scale scores (range) measure physical well-being (0-28), social/family well-being (0-28), relationships with doctors (0-8), emotional well-being (0-20), functional well-being (0-28), and additional concerns (0-36) related to breast cancer. The FACT-B score (0-148) is the sum of the sub-scale scores. Higher FACT-B scores reflect greater well-being.[14]

The Mishel Uncertainty in Illness Scale (MUIS) is a 33-item instrument which measures a person's inability to determine the meaning of illness-related events. Four sub-scales scores (range) measure ambiguity (0-65), complexity (0-35), inconsistency in information provided (0-35), and unpredictability (0-25). The sub-scale scores are added for a total MUIS score (0-160). Higher MUIS scores reflect greater uncertainty.[15]

The Profile of Mood States (POMS) consists of 65 adjectives describing feeling and mood used to identify and assess transient, fluctuating affective states. Six sub-scale scores (range) measure tension-anxiety (0-36), depression-dejection (0-60), anger-hostility (0-48), vigor-activity (0-32), fatigue-inertia (0-28), and confusion-bewilderment (0-28). The vigor-activity sub-scale score is subtracted from the summation of the other five sub-scale scores for a total mood disturbance score (-32-200). Higher POMS scores reflect a greater mood disturbance.[16]

After randomization, the initial set of questionnaires and a prestamped return envelope are given to the participants to be returned within one week. Subsequent sets of questionnaires and return envelopes are mailed at intervals of 1, 3, 6, 12, 18, and 24 months after enrollment and are to be returned within one week of receiving them. Women who do not return questionnaires receive reminder letters mailed after two weeks, telephone calls after four weeks, and additional letters and sets of questionnaires as required.

Costs of Care

Costs of care are being collected from billing information of HealthSystem Minnesota and independent systems who agreed to participate in this study and by collection of episodes of care as recorded by the patient in a diary. The costs of care collected from the billing systems are in the form of charges and reimbursement. These billing system costs include fees for provider procedure and service, room utilization, radiological procedures, laboratory tests, supplies, medications, and some professional fees. The professional fees included are fees for a nurse anesthetist, EKG readings performed by a cardiologist, and physicians' services. Professional fees not included are non-participating physician fees, such as anesthesiologist fees and emergency room physician fees.

The APN costs are measured from the APN logs. APNs complete the logs as they provide care for the subjects at hospitalizations, clinic visits, and home visits. APN time is also recorded for telephone calls, administrative work, and travel for home visits. In addition, travel mileage to homes is recorded.

Analysis

At the completion of the study in 1999, univariate analysis will be performed using student's t-test for continuous variables and the Mantel-Haenszel chi-square test for categorical variables. All p values will be two-tailed and will be considered statistically significant at $p<0.05$. The quality of life mean FACT-B, POMS, and MUIS scores will be graphed over time for the intervention group and the control group. Potential predictors of quality of life include group assignment (intervention versus control); treatment type; and disease and demographic characteristics. In addition, any characteristics which are distributed unequally in the intervention and control groups at baseline despite randomization will be examined.

The costs of care as determined by billing information will be categorized into in-system charges and obtainable out-of-system charges. The in-system charges will include charges and reimbursement for all treatment (biopsies, surgeries, radiation, chemotherapy) at either facility, 610840 (Methodist) or 150 (Park Nicollet), as designated by the oncology registry. In-system charges must also be from HealthSystem Minnesota's oncology-related physicians (general/plastic surgeons, medical/radiation oncologists).

The obtainable out-of-system charges category will include charges for all out-of-system charges obtainable from billing information. Charges defined as out-of-system are those for any portion of treatment (biopsies, surgeries, radiation, chemotherapy) received at a hospital other than Methodist Hospital or from participating independent oncology-related physicians.

Reimbursement data for both in-system and out-of-system charges will come directly from the billing information for hospital charges. Other reimbursement data will be calculated from the charge data by applying a collection factor. A collection factor is based on an individual's insurance type and is determined yearly by the net revenue received from the insurance product divided by gross charges assessed to the insurance product.

APN hospitalization and clinic visits, as well as, telephone, administrative, and travel time, will be obtained from the APN logs for each patient. The cost of the APN intervention will be calculated by using the following formula: APN cost ={[salary + fringe] divided by the number of hours worked} divided by 60 min/hour, taking into account rates of pay and percent time worked for each APN. In addition to the cost per minute from visits, telephone, administrative, and travel time for each patient, a travel cost of 31.5¢ per mile for home care visits will be calculated.

Other outcomes including the non-charge estimates, i.e. frequencies of visits/services, time lost from employment, hospital length of stay, support services, and telephone call estimates, will be obtained from the patients' diaries.

Stratified charge analyses may include analyzing cancer-related vs. non-cancer-related charges defined by ICD-9 codes, treatment, hospitalization charges vs. emergency room charges vs. outpatient services charges, and hospital charges of inpatient vs. 23 hour observation vs. one day surgery.

RESULTS

Of the 561 women with newly diagnosed breast cancer who received initial treatment at HealthSystem Minnesota during the study enrollment period, 85 women were not referred by their physicians (15%) and were not approached about the study. After reviewing eligibility criteria of the 476 referred patients, 180 patients were determined to be ineligible. Patients were deemed ineligible for the following reasons: a previous diagnosis of cancer (n=63), planning to go outside of our system for care (n=46), not enrolling in the study within two weeks of knowing about the diagnosis (n=40), having a comorbidity limiting functional ability (n=12), inability to complete questionnaires (n=8), inability to read and write English (n=4), having a severe psychiatric illness (n=4), and inability to give informed consent (n=3). Eighty-five (28.7%) of the 296 eligible patients refused participation. The enrolled sample of 211 (71/3%) women met eligibility criteria and agreed to participate. The sample includes 106 patients in the intervention group, and 105 patients in the control group. One patient randomized to the control group was restaged to a non-cancerous condition after enrolling and subsequently withdrew from the study decreasing the control group to 104 patients.

Patient Characteristics

Patient characteristics are described in Appendix B. The intervention and control groups were similar at baseline with respect to age at diagnosis, race, marital status, extent of disease (SEER stage[17]), grade, tumor size, nodal and invasive status, method of breast cancer diagnosis, and family history of breast cancer. Women in the intervention group tended to have higher Broder's grades ($p=0.09$) and a greater extent of disease ($p=0.11$) than women in the control group but these differences were not statistically significant. There were differences in income between women in the control and intervention groups ($p=0.02$). Part of the difference may be attributed to the number of women with unknown values.

Preliminary Analysis

Preliminary analysis of the Mishel Uncertainty in Illness Scale (MUIS) scores between the initial and one month questionnaires showed that patients receiving APN care had a significantly better difference in mean scores on the sub-scales of complexity (understanding the system of care), inconsistency (receiving consistent information) and unpredictability (contingency between illness, treatment cues and illness outcome) than the control group ($p<0.01$). Intervention subjects also had a significantly greater improvement in depression-dejection score between the initial and one month scores ($p<0.05$). No other statistically significant differences in scores were found in scores during this time period. (See Appendix C for one month outcomes.) Relationships with predictors such as disease characteristics and treatment choice will be examind in further analysis. Final analysis will be conducted on cost outcomes using charge and reimbursement data and quality of life outcomes using the FACT-B, POMS, and the MUIS.

Rate of Response and Attrition

To date, the response rate for the sets of questionnaires for participants enrolled in the study is 89.8% (837/932). The rate for questionnaire return is closely followed with reminder letters and phone calls to the participants who are not consistently responding.

Attrition is at 11.4% (24/211) and has occurred at about one half the projected rate (20%).

DISCUSSION

Clinical Significance

Although data analyses is preliminary, the APN intervention appears to have improved the understanding of the system of care for women in the intervention group. The Mishel score demonstrated at one month that information for women in the intervention group is perceived to be more consistent and illness, treatment, and treatment outcomes were more

predictable than for the control group in the first month after their diagnosis. This predictability may improve adjustment to the diagnosis and treatment as was suggested in Christman's study of uncertainty during radiotherapy (1990).[19] Johnson, Christman, and Stilt (1985)[20] suggest that information about illness and the patient's ability to anticipate these experiences helps to cope with the situation more effectively. For patients experiencing a myocardial infarction, high levels of uncertainty were directly related to higher emotional stress as patients moved from hospital to home (Christman et al. 1988).[21] Women with the APN intervention may experience decreased levels of uncertainty and less depression and dejection with improved outcomes. These improved outcomes may be associated with lower costs. This relationship has not yet been demonstrated with women with breast cancer. This analysis will be critical to evaluating the hypotheses of this study.

Statement of Work Progression

Work is progressing on schedule as per the statement of work (SOW). Accrual was completed 5/30/97. The refusal rate (n=85, 28.7%) was lower than anticipated when compared with Hughes reported refusal rate of 40% at the time of diagnosis.[18] To date 41 of the remaining 187 women have completed the study. The APN intervention is occurring with each of the women in the intervention group and will be completed 5/99 (month 56) as will data collection and entry of all participants' responses. Analysis of data will occur 5-9/99 with reporting of results at the completion of analysis (month 60). No problems are anticipated with the completion of this work as per contract.

The success of randomization was evaluated by the comparison of baseline characteristics among the intervention and control groups. Residual differences in income will be examined in multivariate analysis. Special attention will be given to participants from the new site to determine if they differ from the participants of the original site. The number of participants from the new site is small (n=3) and the stability of the final results can be examined by alternately excluding and including them from the analyses and comparing the results obtained. This sample is representative of the area in which this study is being conducted. Diversification of our study sample is not anticipated as demographic and cultural diversity in this catchment area is limited.

Additional Study - Phase II

We have proposed an additional study to the USAMRMC based on anecdotal comments which have been made by study participants, family, and health care providers. These comments indicate a high level of satisfaction with the improved quality of care provided by the APNs as well as the multiple hours of physician time saved by the APN interventions. This satisfaction has increased interest in obtaining answers to questions regarding cost savings of the APN interventions. Cost and quality of life outcomes of this study will not be known until 1999, but this study's staff is looking at comparing a shorter, more highly focused intervention to the intervention of the current study. The

new intervention would be tested in a convenience sample of approximately 50 additional women who are newly diagnosed with breast cancer. APN time would be measured and the participant's quality of life responses would be compared to the two groups in the present study. By studying the cost and efficacy of an intensified form of the APN intervention, additional information would be gained on resource utilization. These results would be invaluable to other cancer programs planning to implement this research or allocate resources. Funds already appropriated for this study would be utilized with no other funding requested from the USAMRMC. IRB approval would be obtained. We are pursuing this additional study with the USAMRMC concurrent to the writing of this report and will proceed as advised.

CONCLUSION

This study is progressing as per the statement of work. The intervention, data collection and entry will continue and analysis of data with reporting of results will be completed in 1999. Preliminary analyses indicate women who have received the APN intervention have a significantly greater improvement in understanding the system of care, receiving more consistent information and predictability between illness, treatment, and illness outcomes.

The participant response rate will continue to be followed closely to maintain a good rate of response with continued reminders and encouragement to complete questionnaires at each measurement interval.

Further study with a modified intervention is being actively pursued at our study site and with the USAMRMC. With approval to proceed, this additional study will be completed, with no increase in funding, by 9/99 as agreed upon in the present contract.

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Standard APN
Follow-up Care

	PHASE I INTRODUCTION		PHASE III FOLLOW-UP IF NO TREATMENT
Frequency	**Pre-surgical meeting @ 0-7 days**	**Frequency**	Radiation, Chemo, Surgery, Plastic Surgery
	Introductory meeting		**Weekly contact for status**
1visit; 1 call	Explanation of BCNC role & availability	weekly	Education, support and assessment
1visit; 1 call	Needs assessment form	x 2-24wks	Pain
1visit; 1 call	Decision making process	x 2-24wks	ROM
1visit; 1 call	Physical assessment form with Hx (PRN)	x 2-12wks	Seroma
hospital visit	Give pt. copy history/current meds	x 2-12wks	Necrosis
hospital visit	Library information given	x 2-26 wks	Oral intake (especially with chemo)
hospital visit		x 2-12wks	Infection
	Follow-up-up plan:	ongoing	Fatigue
	Tentative plan of care:	x 2-26 wks	Prosthesis Information
	Obtain arm measurements bilaterally	x 2-26 wks	Blood counts
daily callx1-2wks	Calendar	x 2-26 wks	**Psychosocial support**
wkly callsx6-8	Accompany to MD visits		Mood
1 visit	Next contact with BCNC (date)	ongoing	Coping
ongoing	Contact during hospitalization	ongoing	Energy level
ongoing	Contact during outpatient visit	ongoing	Referral to Social Services PRN
			Referral to Support Groups in community
1-2 visits	**PHASE II POST OP**	ongoing	**BCNC support during any/all visits**
1-3x/week	**Home visit post-op 24-48 hrs**	ongoing	surgeon, plastics, oncologist, radiation
	Telephone contact during 1st 3-5 days		
	Education	ongoing	**Follow-up visit @ 4-6 weeks (all pts)**
x 1	Signs of infection/inflammation		Physical assessment
daily x 7	Temp		Arm measurements
daily x 7	JP Stripping /Drainage / leakage/	x1-2 visits	Review signs/symptoms of lymphedem
daily x 7	Incisional Pain	PRN	Body image-looked in mirror?
daily x 7	Swelling	x1 or PRN	Prosthesis
daily x 7	Redness	x1 or PRN	Sexuality
daily x 7	Arm ROM/ pain / burning	x1 or PRN	Back to work or normal activity yet?
daily x 7	General well-being	x1 or PRN	Told others?
daily x 7	Mood	1-24 wks	Family
daily x 7	Fatigue	1-4 wks	Friends
daily x 7	Energy level	1-4 wks	Co-workers
daily x 7	Appetite	1-4 wks	Support group?
daily x 7	Comfort/pain control/ constipation	1-24 wks	**Follow-up with oncologist**
weekly	Coping with life and home	ongoing	Support
weekly	Spouse/significant other	ongoing	Treatment discussion
weekly	Family issues	ongoing	Options
weekly	Children	ongoing	Reinforce education
weekly	Child care	ongoing	Wigs
weekly	Job/career	2-24wks	Cosmetics/hair care
weekly	Housework	ongoing	Fatigue management
X1	**Have they met with reach to recovery**	ongoing	Hot flashes and management
weekly	Exercise/ review with pt /	ongoing	**Follow-up with Plastic Surgeon**
x2	Prosthesis	ongoing	Monitor for necrosis
	Follow-up surgeon visit date?	ongoing	Monitor for infection
5 visits/ ongoing	**Medical plan of care:**	ongoing	Assess for normal ADL's
	RT	ongoing	Pain control with saline expansion
	Chemo	ongoing	Plan for secondary surgery PRN
	Additional Surgery		
	Next FU visit scheduled?		

Standard APN
Follow-up Care

	PHASE III TREATMENT MANAGEMENT		PHASE IV FOLLOW-UP CARE
Frequency		**Frequency**	
monthly FU	**Tamoxifen**		Telephone contact every other wk x 4
0-2 yrs	Side effects: Hot flashes, weight,		(every week x 4 if no treatment; then qow
	mood swings, endometrial ca risk	ongoing	Monthly FU phone calls or visits for all pts
	GYN evaluation if spotting	ongoing	Lymphedema FU every 3 mos x 4; then q 6
daily x1-3	**Chemo: Call day 1,2,3**	ongoing	BSE instruction with return demo PRN
weekly 0-32	Assess nausea, fatigue, diet, activity,		give shower cards, stickers
& monthly	diarrhea, constipation, mouth sores	ongoing	Mammogram scheduled annually
	Blood counts	ongoing	Stress importance of BSE and FU care
	Educate regarding plan & ttment delays	monthly	**ISSUES: support, assess and educate**
FU weekly	**Radiation Therapy:**	ongoing	Diet
0-10 weeks	Assess skin reaction, fatigue,	ongoing	Exercise
	blood counts	ongoing	Weight
0-10 weeks	Educate regarding ttment plan and FU	ongoing	Hot flashes
		ongoing	Sexuality
monthly	**Educational reinforcement**	ongoing	Pregnancy
ongoing	**Frequency of healthcare visits:**	ongoing	Work Issues
ongoing	Strategy for coping	ongoing	Menopause
ongoing	Activity adjustment	ongoing	Insurance coverage
ongoing	Fatigue management	ongoing	Medication cost
		ongoing	Venous access device management
monthly	**Activity of daily life**	ongoing	Late treatment effects
ongoing	Ability to perform ADL's	monthly	**Health Promotion**
ongoing	Appearance	ongoing	Quit smoking
ongoing	Fatigue	ongoing	Diabetic control
ongoing	Energy level	ongoing	Assess hypertension
ongoing	Change from precancer level of activity	ongoing	Dietary modifications
ongoing	Diet adjustment	ongoing	Stress reduction
ongoing	Oral rinse and mouth care	monthly	**Complementary therapies**
ongoing	Fluid intake	ongoing	Stress management
ongoing	Monitor output	ongoing	Imagery
ongoing	Taste changes	ongoing	Positive thinking
ongoing	Weight gain/loss	ongoing	Support groups
ongoing	Social adjustment	monthly	**Recovery**
ongoing	Sick leave availability	ongoing	Taking control/proactive
ongoing	Child care issues	ongoing	Fear of recurrence
ongoing	Transportation to treatment	ongoing	Coping
ongoing	Cooking	ongoing	Spirituality
ongoing	Cleaning	ongoing	Hope
ongoing	Laundry	monthly	**Psychosocial assessment:**
ongoing	Shopping	ongoing	Kids
ongoing	other	ongoing	Sex
monthly	**Physical side effects**	ongoing	Work
ongoing	Skin care:	ongoing	Home
ongoing	Rashes	ongoing	Reconstruction
ongoing	Incision	ongoing	Future plans
ongoing	Dryness	ongoing	Social Services referral PRN
ongoing	Neuropathy		
ongoing	Status of surgical site		

TABLE 1. PATIENT CHARACTERISTICS AT DIAGNOSIS

VARIABLE	INTERVENTION GROUP n=106	CONTROL GROUP n=104	P VALUE
Median age at diagnosis (yr)	54	53.5	0.81
Median years of education	14 (n=103)	14 (n=91)	0.61
Median tumor size (cm)	1.7 (n=93)	2.0 (n=98)	0.85
Median no. of nodes removed	18	16	0.34
Median no. of positvie nodes	0	0	0.32
		n (%)	
Age (yr)			0.71
<40	9 (8.5)	11 (10.6)	
40-49	24 (22.6)	25 (24.0)	
50-59	34 (32.1)	31 (29.8)	
60-64	15 (14.1)	10 (9.6)	
65-74	20 (18.9)	18 (17.3)	
75-84	4 (3.8)	8 (7.7)	
>84	0 (0.0)	1 (1.0)	
Race			0.90
White	103 (97.2)	101 (97.0)	
Asian	2 (1.9)	1 (1.0)	
African American	1 (0.9)	1 (1.0)	
American Indian	0 (0.0)	1 (1.0)	
Marital Status			0.76
Single, never married	11 (10.4)	15 (14.4)	
Married	74 (69.8)	70 (67.3)	
Divorced	8 (7.5)	9 (8.7)	
Widowed	13 (12.3)	10 (9.6)	
Income			0.02
Below $10,000	3 (2.8)	0 (0.0)	
$10,000-30,999	21 (19.8)	26 (25.0)	
$31,000-50,999	22 (20.8)	22 (21.2)	
$51,000-70,999	21 (19.8)	7 (6.7)	
$71,000-90,999	11 (10.4)	17 (16.3)	
$91,000 or more	18 (17.0)	14 (13.5)	
Not provided	10 (9.4)	18 (17.3)	
Extent of disease			0.11
In situ	12 (11.3)	8 (7.7)	
Localized	49 (46.2)	65 (62.5)	
Regional	43 (40.6)	29 (27.9)	
Distant	2 (1.9)	2 (1.9)	
Tumor Size			0.24
< 2 cm	50 (47.2)	47 (45.2)	
2 - 5 cm	37 (34.9)	47 (45.2)	
>5 cm	6 (5.7)	4 (3.8)	
Unknown	13 (12.2)	6 (5.8)	
No. of positive nodes			0.25
None	65 (61.3)	75 (72.1)	
1-3	26 (24.5)	18 (17.3)	
>3	15 (14.2)	11 (10.6)	
Histology			0.37
Non-invasive	12 (11.3)	8 (7.7)	
Invasive	94 (88.7)	96 (92.3)	
Broder's Grade			0.09
Grade 1, well differentiated	15 (14.2)	14 (13.5)	
Grade 2, moderately differentiated	54 (50.9)	42 (40.4)	
Grade 3, poorly differentiated	29 (27.4)	44 (42.3)	
Grade 4, undifferentiated	7 (6.6)	2 (1.9)	
Unknown, not applicable	1 (0.9)	2 (1.9)	
Method of breast cancer diagnosis			0.47
Regular self exam	21 (19.8)	27 (26.0)	
Doctor	9 (8.5)	9 (8.6)	
Incidental by patient	22 (20.8)	14 (13.5)	
Mammogram	54 (50.9)	54 (51.9)	
Family history of breast cancer			0.39
Yes	46 (43.4)	50 (48.1)	
No	49 (46.2)	39 (37.5)	
Unknown	11 (10.4)	15 (14.4)	

Differences Between Baseline and One Month Mean Scores for Mishel Uncertainty in Illness Scale (MUIS), Profile of Mood States (POMS), and Functional Assessment of Cancer Therapy - Breast Cancer (FACT-B).

Questionnaire	Variable	Intervention group mean difference	Control group mean difference	p value
MUIS*	Total Score**	2.594	-5.915	0.001
	Ambiguity	0.573	-2.341	0.054
inter. n=96	Complexity**	1.083	-0.963	0.001
control n=82	Inconsistency**	1.438	-0.354	0.005
	Unpredictability**	-0.5	-2.256	0.009
POMS*	Total Mood Disturbance	17.33	10.704	0.150
	Tension-Anxiety	5.67	4.593	0.307
inter. n=97	Depression-Dejection***	5.598	2.901	0.032
control n=81	Anger-Hostility	2.588	1.494	0.276
	Vigor-Activity	-0.351	-0.099	0.795
	Fatigue-Inertia	-0.093	-0.667	0.516
	Confusion-Bewilderment	3.216	2.284	0.217
FACT-B*	Total Score	0.735	4.026	0.132
	Physical Well-Being	1.9	2.754	0.294
inter. n=95	Social/Family Well-Being	-0.525	0.305	0.140
control n=82	Relationship With Doctor	-0.032	-0.22	0.369
	Emotional Well-Being	-2.414	-1.902	0.225
	Functional Well-Being	0.802	1.634	0.304
	Additional Concerns	1.003	1.456	0.461

* A positive score indicates an improvement in the MUIS total score and sub-scales, the POMS total score and sub-scales except vigor-activity. A negative score indicates an improvement in the FACT-B scores and the vigor-activity subscale of the POMS.

** $p < .01$

*** $p < .05$

ACRONYM AND ABBREVIATION DEFINITIONS

APN	-	Advanced Practice Nurse
ACSCC		American College of Surgeons Commission on Cancer
EKG	-	Electrocardiogram
ER	-	Emergency Room
FACT-B		Functional Assessment of Cancer Therapy - Breast Cancer
HIV	-	Human Immunodeficiency Virus
MI	-	Myocardial Infarction
MUIS		Mishel Uncertainty in Illness Scale
POMS		Profile of Mood States